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Dated: August 18, 2004

Signature: Shawn P. Foley  
(Shawn P. Foley)

Docket No.:  
CELLTH 3.0-003 CONT CONT XVI  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Warrell et al.

Application No.: 10/759,290

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: PROCESS FOR PRODUCING ARSENIC  
TRIOXIDE FORMULATIONS AND  
METHODS FOR TREATING CANCER USING  
ARSENIC TRIOXIDE OR MELARSOPROL

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### **REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)**

Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By Shawn P. Foley  
Shawn P. Foley  
Registration No.: 33,071  
LERNER, DAVID, LITTBENBERG,  
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### INFORMATION DISCLOSURE STATEMENT

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

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08/25/2004 GWORDOF1 00000017 121095 10759290  
01 FC:1806 180.00 DA

No. 12-1095.

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Substitute for form 1449A/B/PTO

**Complete if Known****INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XVI
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**0 U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA**	US-132,275-B1	10-15-1872	Gettings		
AB**	US-232,807	10-05-1886	Dennett		
AC**	US-3,700,498	10-24-1972	Kanazawa et al.		
AD**	US-4,497,780	02-05-1985	Barin et al.		
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AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong		
AH**	US-6,770,304	08-03-2004	Warrell et al.		
AI**	US-2003/0099719	05/2003	Warrell et al.		
AJ**	US-6,723,351	04-20-2004	Warrell et al.		
AK**	US-6,773,792	05-11-2004	Lu		

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
BA	JP-51-88620		03-08-1976			
BB	WO-95/01789		01-19-1995			
BC	CN-1133725		10-23-1996			
BD	CN-1131037		09-18-1996			
BE	CN-1122700		05-22-1996			
BF	CN-1081104		01-26-1994			
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BH	CN-1061908		06-17-1992			
BI	CN-1121807		05-08-1996			
BJ	CN-1079391		12-15-1993			
BK	WO-94/02103		02-03-1994			
BL	FR-2 539 993		03-31-1994			
BM	DE-43 17 331		12-01-1994			
BN	WO-95/22336		08-24-1995			
BO	LV-11667		06-20-1997			
BP	WO-94/02108		02-03-1994			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878		
CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogenous leukemia", Jour.		

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
				Application Number	10/759,290
				Filing Date	January 16, 2004
				First Named Inventor	Raymond P. Warrell, Jr.
				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	2	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XVI

		A.M.A. 97(1):3-5, 1931	
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	CS	LI et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma", Chinese J. Oncology, 10:61-62, 1988	
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				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	3	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XVI

	CD1	CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia: As <sub>2</sub> O <sub>3</sub> induces NB <sub>4</sub> Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR $\alpha$ /PML proteins", Blood 88(3): 1052-1061, Aug. 1996. ©American Society of Hematology 1996	
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	CS1	REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol. Suppl. 13, p. 363-65, 1989	
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Sheet	4	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT XVI

	CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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